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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,402	12/28/2001	Hitoshi Matsumoto	VX012397 PCT	3876

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POSZ LAW GROUP, PLC
12040 SOUTH LAKES DR.
SUITE 101
RESTON, VA 20191

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,402	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-30 and 32-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-30 and 32-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 February 2005 has been entered.

Claims 27-30 and 32-35 and 37-39 have been amended and claim 31 has been canceled. New claim 41 has been added. Claims 27-30 and 32-41 are pending to which the following grounds of rejection are or remain applicable. Note please that claims 36 and 40 are indicated as being "currently amended". There does not appear to be an amendment entered since the amendment filed on 23 April 2004. Thus, these claims should be referenced as "previously presented".

Claim Objections

Claims 37 and 38 are objected to because of the following informalities: the claims, as currently amended are unclear. Currently, claim 37 reads "The black currant anthocyanin-containing food composition suitable for human consumption according to claim 27, which contains an effective amount of the black currant anthocyanin for improving visual function **of** alleviating asthenopia and/or improving adaptation to darkness. Is this a Markush group? If so, it should read "The black currant anthocyanin-

containing food composition suitable for human consumption according to claim 27, which contains an effective amount of the black currant anthocyanin for improving visual function **selected from the group consisting of** alleviating asthenopia and/or improving adaptation to darkness. Claim 38 is similarly flawed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 36, 38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification gives numerous examples for lowering blood pressure and improving blood fluidity, however it does not provide a written description for the conditions associated with the term "health-promoting. The term "health-promoting" is not found in the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "including" in claim 35 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "health-promoting" in claims 35, 36, 38 and 40 is a relative term which renders the claim indefinite. The term "health-promoting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how unhealthy a one's health can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "health-promoting" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term "improving visual function" in claims 37 and 38 is a relative term which renders the claim indefinite. The term "improving visual function" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how un-improved the visual function can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "improving" the metes and bounds of the term are not clear,

making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term "improving adaptation to darkness" in claim 38 is a relative term which renders the claim indefinite. The term " improving adaptation to darkness " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "un-improved" the darkness adaptation can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "improving" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term "improving blood fluidity" in claims 39 and 40 is a relative term which renders the claim indefinite. The term "improving blood fluidity " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "un-improved" blood fluidity can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "improving" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

The term "lowering blood pressure" in claims 39 and 40 is a relative term which renders the claim indefinite. The term "lowering blood pressure" is not defined by the

claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since no guidance is provided as to how "high" the blood pressure can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "lowering" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawhon et al. US. Patent No. 4,643,902.

Lawhon et al. teach a method of producing sterile and concentrated juices with improved flavor and reduced acid. The reference teaches treatment of the filtered juice by reverse osmosis (RO) to concentrate the flavor and aroma components in the RO retentate. The concentrated flavor and aroma components can then be recombined with the UF retentate to provide a juice suitable for storage or removed in the concentrated from for later dilution before use. The acid content of the juice can be reduced by passing a portion of the RO retentate through an ion-exchange column (column 3, lines 15-30). The process is broadly applicable to food juices such as currants (column 3, lines 50-66).

It differs in that it teaches currants. The instant application teaches black currants.

The process of the instant application is drawn to the process of producing the juice. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel*

158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since the process is applicable to currants one of ordinary skill in the art would have been motivated to employ the method of extracting the juice from black currants by reverse osmosis and/or ion-exchange resin since Lawhon et al. teach it to be useful to produce juice from currants.

2. Claims 27-29, 35-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lawhon et al. U.S. 4,643,902 (A) in view of Nakhmedov et al. (Konservnaya I Ovoshchesushil'naya Promyshlennost (U) and Laboratoires Chibret, Societe Anonyme, GB 1,007,751 (N).

Lawhon et al. teach purifying and concentrating juice such as currant juice through by reverse osmosis and optionally by ion exchange resin. It does not teach black currants. It would have been obvious to substitute black currant juice instead of currant juice since Lawhon et al. teach the reverse osmosis and ion-exchange to be employed for currant juice. It is prima facie obvious to substitute equivalents motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since the process is applicable to currants one of ordinary skill in the art would have been motivated to employ the method of extracting the juice from black currants

by reverse osmosis and/or ion-exchange resin since Lawhon et al. teach it to be useful to produce juice from currants.

Lawhon et al. does not teach the percent solids in the black currant material for food. Nakhmedov et al. teach that wastes from black currant contained 5 to 10% solids, which is encompassed by the instantly claimed 5 to 25%. Regarding the delphinidin-3-o-rutinoside, it is known that delphinidin 3-rutinoside is contained in the anthocyanin of black currant fruit as recited by Nakhmedov et al. (see abstract).

Regarding claims 37 and 38, drawn to the composition for improving visual function, of alleviating asthenopia and/or improving adaptation to darkness, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"The patentability of a product does not depend upon its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence

establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Laboratoires Chibret Societe Anonyme teach that anthocyanin glucosides such as those obtained from bilberries are useful for visual acuity enhancing night vision (column 1, lines 20-25). It would have been obvious to employ black currant anthocyanin for vision problems such as visual acuity and night vision. Motivation to employ black currants would come from the knowledge that Laboratoires Chibret Societe Anonyme teach anthocyanins such as those obtained from bilberries to be useful for such a purpose. It is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious. *In re Font*, 213 USPQ 532. Since both bilberries and black currants contain anthocyanin, it would have been obvious to employ black currants to improve vision since Laboratoires Chibret Societe Anonyme teach anthocyanin containing vegetable extracts of fruit juices to be useful for such a purpose.

Response to Arguments

Applicant asserts that the use of the language, such as "an effective amount" including the desired property or effect has long been recognized as acceptable in U.S. Patent practice and cites In re Halleck, 164 USPQ 647, 57 CCPA 954 (CCPA 1970) as

evidence of this assertation. It is not clear to the examiner whether "an effective amount" is drawn to a method claim or a composition claim. Applicant currently has composition claims and process of making claims. *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) states that the intended use of an old composition does not render composition claim patentable; *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969) states that the mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a one step process vs a 2 step process) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 27-29 and 35-41 are drawn to a composition. Claims 30 and 32-34 are drawn to a process of producing black currant anthocyanin-containing food compositions. There is no indication in the claims that the process differs or is an improvement over Lawhon's process. Further, various manipulations of process steps have been recognized as obvious. See *In re Tatincloux* 108 USPQ 125 (CCPA) 1955 wherein the board correctly found that, generally, no invention is involved in broad concept of performing simultaneously operations which have previously been performed in sequence; exception may be made where new and unexpected result is obtained by performing operations simultaneously.

The examiner has taken note of the explanation regarding the expression in the claims "on the basis of solid matters".

Objection to claim 33 is no longer maintained in view of the amendment that changes absorb to adsorb.

The examiner has taken note of the explanation regarding the Japanese prior art discussed in the instant specification on page 19.

The rejection 35 U.S.C. §112 2nd paragraph over claims 37-40 is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth above. As stated above, since no guidance is provided as to how un-improved the visual function can be or how high the blood pressure can be and still fall within the scope of the instantly claimed subject matter as circumscribed by the term "improving" or "lowering" the metes and bounds of the term are not clear, making it impossible to ascertain with reasonable precision when that term is infringed and when it is not. Applicant asserts that the subject matter is in the instant specification. The examiner could find no information regarding these statements other than the phrase "lowering blood pressure" or "improving blood fluidity" It is further questioned what is meant by "improving blood fluidity". Anticoagulation is the term used to describe the process that makes a patient's blood less likely to clot. Under normal circumstances, if blood is allowed to stand for a short period of time, it will form a clot. **Blood clotting is a normal body process, which protects the body from serious damage.** It helps to assure that when the body is injured, any resulting bleeding will be minimized as a clot forms at the site of the broken blood vessel. There are many types of anticoagulation therapy

with many different aims. One is with aspirin therapy. Aspirin therapy causes aspirin-induced inactivation of platelet prostaglandin G/H synthase, which results in maximal inhibition of thromboxane-dependent platelet aggregation and prolongation of the bleeding time. Warfarin is another agent used for anti-coagulation. The specific action of warfarin is to block the production of Factors VII, IX, X, and II by the liver. Creation of these factors by the liver is normally controlled by Vitamin K. Administration of warfarin sodium blocks the action of vitamin K within the liver. The drug effectively competes for the same absorption sites within the liver needed for vitamin K uptake. Thus the levels of vitamin K within the liver decrease. Reduced amounts of clotting factors VII, IX, X, and II are produced, and the clotting action of the blood is progressively impaired. Heparin is another agent generally used for anticoagulation. Heparin works by potentiating the action of antithrombin III, as it is similar to the heparin sulfate proteoglycans which are naturally present on the cell membrane of the endothelium. Because antithrombin III inactivates many coagulation proteins, the process of coagulation will slow down. The effects of heparin, coumadin and aspirin can be measured in the lab by the partial thromboplastin time (APTT), (the time it takes the blood plasma to clot. How is anthocyanin measured? Also, it is unclear to the examiner why "improving blood fluidity" is desirable since the clotting of blood is a normal body process that protects the body from serious damage (is this to a patient in need of anti-coagulation, such as a stroke patient?). The same objections arise with the term "lowering blood pressure". Is this lowering of blood pressure to a patient with high blood pressure that is in need of lowering?

Regarding applicant's arguments concerning the charged reverse osmosis membrane, although, Lawhon does not specifically recite a "charged" reverse osmosis (RO) membrane, example 4 in column 10 recites that the RO membrane system is stated to have a 99% rejection for NaCl. It is well known in the art that reverse osmosis is capable of rejecting bacteria, salts, sugars, proteins, particles, dyes, and other constituents that have a molecular weight of greater than 150-250 daltons. The separation of ions with reverse osmosis is aided by charged particles. This means that dissolved ions that carry a charge, such as salts, are more likely to be rejected by the membrane than those that are not charged, such as organics. The larger the charge and the larger the particle, the more likely it will be rejected. Since the invention of Lawhon et al. rejects 99% NaCl, then the RO membrane is aided by charged particles. Applicant's own specification indicates that with an uncharged reverse osmosis membrane having a salt retention rate of from 30 to 99% and further states that reverse osmosis membranes used in this process are an uncharged type (page 5, 2nd full paragraph). Since Lawhon rejects 99% NaCl, it is readily apparent that Lawhon is using a charged RO membrane. Applicant's assertions regarding the process claims are not reflected in the instant claims. If applicant is claiming that anthocyanins, without water, sugars and acids are obtained by the instant process, it is not reflected in the instant claims.

Regarding the Nakhmedov translation, applicant asserts that the black currant anthocyanin contains only 0.8 to 2% of anthocyanin. However, please note that in the

same chart, the quantity of anthocyanins in coloring agent produced from marc is between 5% and 6.2%, which is still encompasses in the instant claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/01/2005